UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 09-CV-10547; and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698.	Judge Patti B. Saris

UNITED STATES' MEMORANDUM IN SUPPORT OF ITS OPPOSITION TO THE MOTION TO APPROVE THE PROPOSED SETTLEMENT BETWEEN SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION, WARRICK PHARMACEUTICALS CORPORATION, CALIFORNIA, FLORIDA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS

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The United States submits this memorandum in opposition to the motion to approve the proposed settlement between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation (collectively "Schering/Warrick"), the States of Florida and California, and Relator Ven-A-Care of the Florida Keys (collectively "the Settling Parties").

Pursuant to 31 U.S.C. § 3730(b)(1), the United States has an absolute veto authority over the voluntary settlement of a *qui tam* action. *See United States v. Health Possibilities*, 207 F.3d 335, 339 (6th Cir. 2000) (holding that a "relator may not seek voluntary dismissal of any qui tam action without the Attorney General's consent."); *Searcy v. Phillips Electronic North America Corp.*, 117 F.3d 154, 160 (5th Cir. 1997) (holding that the government has an absolute veto

authority of voluntary dismissals of False Claims Act *qui tam* actions); *United States v. Globe Composite Solutions v. Solar Construction*, 528 F.Supp. 2d 1, 6-7 (D. Mass. 2007) (concurring with Fifth and Sixth Circuits that the United States has absolute veto authority). Indeed, "the power to veto a privately negotiated settlement of public claims is a critical aspect of the government's ability to protect the public interest in *qui tam* litigation." *Health Possibilities*, 207 F.3d at 340.

In this case, the United States formally withholds its consent to the settlement proposed by the Settling Parties. Because there can be no settlement absent the United States' consent, there is nothing for the Court to approve or disapprove, and certainly nothing requiring the Court to render any findings of fact or rulings of law. For similar reasons, there is no settlement agreement for the Court to evaluate for purposes of fairness, adequacy, or reasonableness. Issuing findings of fact or rulings of law in this context would surely constitute nothing short of an advisory opinion.

While the Government's veto authority is absolute and not subject to judicial review, the United States believes it has sound reasons for objecting to the proposed settlement and shares some of those reasons below. Nevertheless, while the United States does not consent to the proposed settlement, it remains ready to work with the Settling Parties, as well as the other litigating states, to reach a global resolution.

ARGUMENT

I. The Government Has the Absolute Right To Veto the Voluntary Dismissal of a Qui Tam Action

The False Claims Act authorizes a private person to bring an action "in the name of the Government" to seek civil remedies for fraud against the United States. 31 U.S.C. § 3730(b)(1). Among the conditions placed on the relator's right to bring suit on behalf of the United States, however, is that a *qui tam* action "may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id*.

This statutory language "is as unambiguous as one can expect," requiring the consent of the Attorney General before the case can be dismissed. *Searcy*, 117 F.3d at 159. In light of this clear language, both the Fifth and Sixth Circuits have held that the False Claims Act grants the United States the unfettered authority to "stand on the sidelines" and then to "veto" a settlement that would result in dismissal of the case. *Id*. at 158-60; *Health Possibilities*, 207 F.3d at 339. In doing so, both courts rejected the reasoning of the Ninth Circuit's decision in *United States ex rel. Killingsworth* v. *Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994), which had held that the Attorney General's consent to dismissal is required only during the initial 60-day period in which the United States decides whether to intervene and prosecute the action.[1]

In *Health Possibilities*, 207 F.3d at 339, the Sixth Circuit held that "a relator may not seek voluntary dismissal of any *qui tam* action without the Attorney General's consent." In that case,

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[1] To the extent there was any remaining question as to this right, the Supreme Court appears to have laid that issue to rest in *United States ex rel. Eisenstein v. City of New York*, where it included the government's right to "vet[o] a relator's decision to voluntarily dismiss the action" among the specific rights enjoyed by the government after it declines to intervene in a qui tam action. 556 U.S. __, 129 S.Ct. 2230 (2009).

the United States initially declined to intervene in a *qui tam* action, but objected to the relator's subsequent decision to dismiss the action pursuant to a settlement that the United States believed was not in the public interest. The district court had held that the provision requiring the Attorney General's consent to dismissal applied only during the initial intervention period, and that the United States may object to dismissal only by seeking "good cause" intervention. *Id*. at 338.

The Sixth Circuit reversed, holding that the district court's approach contravened the plain language of the statute. The Court explained that "section 3730(b)(1) unqualifiedly provides that a *qui tam* action 'may be dismissed only if the court and the Attorney General give written consent,'" and found that "[i]f Congress had wanted to limit the consent requirement to the period before the United States makes its initial intervention decision, we presume that it knew the words to do so." *Id*. at 339.

The *Health Possibilities* court also found that the "clear import of the statutory language is strengthened by the FCA's purpose, structure and legislative history." *Id*. at 340. As the court explained, because the interests of the relator and the Government often diverge, "the power to veto a privately negotiated settlement of public claims is a critical aspect of the Government's ability to protect the public interest in *qui tam* litigation." *Ibid*. Without the power to consent to a dismissal, "the public interest would be largely beholden to the private relator who – absent 'good cause' Government intervention – would retain sole authority to broadly bargain away government claims." *Id*. at 341. The court therefore concluded that "the policies served by the veto power are entirely consistent with the conclusion compelled by section 3730(b)(1)'s plain

meaning: that a relator may not settle any *qui tam* action without the Attorney General's consent." *Id.*

The court in *United States ex rel. Globe Composite Solutions v. Solar Construction*, 528 F.Supp.2d 1 (D. Mass. 2007), also joined the Fifth and Sixth Circuits in holding that the Government enjoys an absolute right to veto a voluntary dismissal. In the *Solar Construction* case, the relator and defendants sought to dismiss the claims of the United States with prejudice. *Id.* at 2. The Government objected because its consent had not been obtained. *Id.* The court agreed with the Government and held that "[t]he Government must consent to all dismissals in a qui tam action brought by a private person, even voluntary dismissals by the plaintiff-relator." *Id.* at 6. Given the plain language of Section 3730(b)(1), the court held that it did "not have the authority to dismiss the action with prejudice as to the claims of the United States because the Government has not consented to such dismissal." *Id.* at 6-7.

In this case, the United States exercises its absolute veto right and withholds its consent to the proposed Settlement. Absent the Government's consent, there is no "settlement" for the Court to consider and therefore no basis or need for the Court to render the findings of fact or rulings of law contemplated by the proposed settlement.

As the United States previously noted, given that the Relator and Schering/Warrick do not appear to disagree with regard to Schering/Warrick's potential liability under the False Claims Act in connection with the Schering brand drugs, there is no case or controversy for the Court to adjudicate and that the proposed findings of fact and rulings of law would constitute advisory opinions. *See Overseas Military Sales Corp. v. Giralt-Armada*, 503 F.3d 12, 16 (1st Cir. 2007); *Osediacz v. City of Cranston*, 414 F.3d 136, 139 (1st Cir. 2005). Now that the United

States has formally withheld its consent and there is no "settlement" for the Court to approve, any findings of fact or rulings of law in connection with the Schering branded drugs surely would be advisory in nature.

II. The Government Objects to the Proposed Settlement and Voluntary Dismissal of the Florida and Massachusetts Qui Tam Actions

A. The United States Objects To the Court Making Findings of Fact and Rulings of Law Regarding the Schering Brand Drugs

Interestingly, the driving force behind this settlement is not the resolution of Warrick's FCA liability for the albuterol sulfate drugs, which was the Government's primary focus for the duration of its investigation. Rather, the focus of the proposed Settlement is clearly the Schering Covered Drugs, which were added just recently to the Florida Civil Action and over which there is no apparent conflict between the Relator and Schering/Warrick. Indeed, the Relator evidently included the Schering Covered Drugs in the proposed Amended Complaint not to allege fraud, but for the sole purpose of *not* alleging fraud under the FCA and to assist Schering achieve "finality" in its AWP litigation. *See* Joint Memorandum in Support of Motion for Approval of the Settlement Between California, Florida, and Relator Ven-A-Care of the Florida Keys on Behalf of Itself and the United States and Schering-Plough, Schering and Warrick at 7 ("Joint Memo")(Aug. 7, 2009)(Dkt. 6360, Sub. 355)("[T]o achieve finality with regard to Schering's brand drugs, the Complaint was amended to include the Schering Covered Drugs."). The only part of the proposed Amended Complaint to address the Schering Covered Drugs provides as follows:

> Ven-A-Care has investigated additional drugs marketed by [Schering/Warrick] during the relevant period of time. Those additional drugs are hereinafter referred to as "Schering Brand

> Drugs" and are listed in Exhibit F. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for Schering Brand Drugs because [Schering/Warrick[did not materially misstate the drug price report for those drugs. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because [Schering/Warrick] caused AWPs to be reported that were within 25% of the Wholesaler's Acquisition Cost (subject to at most a 5% discount off of WAC) and thus did not materially misstate the drug price report for those drugs.

Relator Ven-A-Care of the Floriday Keys, Inc.'s Amended Complaint Against Schering Corporation, Schering-Plough Corp., and Warrick Pharmaceuticals Corp. For Violations of the False Claims Act, 31 U.S.C. § 3729 ("Proposed Amended Complaint") (July 21, 2009) (Dkt. #6273, Sub. 284, Exh. 1, ¶ 76). Based upon the inclusion of this statement, Schering/Warrick seek as a condition to the proposed settlement, not merely the release of the United States' claims regarding these drugs, which is the most it would receive in a direct settlement with the United States. Instead, Schering/Warrick require the Court to make certain findings of fact and rulings of law, including that "neither the WACs nor AWPs for [the Schering Covered Drugs] constitute false claims within the meaning of the False Claims Act and that claims for reimbursement based on such WACs and AWPs are neither deceptive nor unfair." Proposed Settlement Agreement and Release (June 26, 2009) (Dkt. #6173, Sub. #231, Exh. A, at 10, ¶ III(6)).

Additionally, Schering/Warrick propose the following findings of fact:

> [T]hat it has long been understood that, historically, the AWPs reported by the national drug pricing compendia (*i.e.,* FDB Bluebook, Redbook, and Medispan) for brand drugs typically represented an industry-wide, formulaic mark-up of 20% or 25% over the wholesale acquisition cost or WAC for that drug. Furthermore, the Court finds that it was widely understood in the industry, by the early 1990's, that some limited discounting off of

> WAC (typically, 2% to 5%) was generally available for brand drugs . . . .
>
> [T]hat government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price for that drug (measured, conservatively, by Average Manufacturers Price or AMP calculated in accordance with all applicable HCFA/CMS regulations) to constitute a false or fraudulent statement, or to be misleading, deceptive, or unfair . . . .
>
> * * *
>
> [T]hat none of the WACS or AWPs for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive, or unfair . . . .
>
> * * *
>
> That the Relator has not sought to recover Medicaid proceeds for the Schering Covered Drugs where the AWP did not regularly exceed the average selling price by more than 30%; that the "yardstick" approach used by the Relator screened out brand drugs where the AWP was no more than 25% above a non-fictitious WAC and accepted as a "non-fictitious" a reported WAC that was no more than 5% above the drug's average selling price; and that this "approach to the settlement agreement of [the Florida Civil Action] under the False Claims Act to be reasonable and fair . . . .

Proposed Order Approving Settlement and Dismissal With Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (June 26, 2009) (Dkt. #6173, Sub. #231, Exh. C, at 5-7).

As noted in our earlier filing, the Government objects to all the proposed findings of fact regarding the federal payors. Schering/Warrick have not provided an evidentiary basis for the Court to make any factual findings on whether a government payor, such as Medicaid, knew when a published AWP was within 30% of the average selling price or the average manufacturer

price, much less considered whether such an AWP is false, fraudulent, misleading, deceptive, or unfair.[2] As both the Court and Schering/Warrick are well aware, an extensive amount of discovery has been taken in connection with the three *qui tam* actions in which the United States has intervened and the relevance of that discovery for purposes of establishing "government knowledge" is still very much in dispute.[3] To the extent the Court must make any findings with regard to the federal or state governments' knowledge, considerations, or expectations, it should do so in the context of a fully developed factual record, not in the context of consenting to a proposed False Claims Act settlement.[4] While the Government appreciates Schering/Warrick's

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[2] The breadth of Schering/Warrick's request is highlighted by the fact that they seek findings that the reported prices were not "misleading, deceptive, or unfair," when those terms are not even part of the federal False Claims Act, 31 U.S.C. §§ 3729-3733.

[3] Schering/Warrick contend that, as a result of having to litigate in the assorted state proceedings, they have "been denied direct discovery of CMS on such critical issues as the federal government's knowledge and understanding of AWP as it reviewed and approved state reimbursement formulae according to which the federal-share was calculated and paid." Affidavit of Beth Trent, at 8 (Aug. 7, 2009)(Dkt. 357). The United States notes that representatives of Schering-Plough had the opportunity to, and did in fact, participate in many of the depositions of key CMS Medicare and Medicaid employees. Among the depositions attended by Schering-Plough were Bruce Vladek (May 4, 2007; July 21, 2007); Linda Ragone (April 17-18, 2007); Sue Gaston (January 24, 2008; March 19, 2008); Charles Booth (April 23, 2007, October 29, 2007); Deidre Duzor (October 30, 2007, February 27, 2008, March 26, 2008); Larry Reed (September 27, 2007; March 20, 2008; March 24, 2008; October 2, 2008; October 22, 2008); Nancy Ann Min DeParle (May 18, 2007, December 5, 2007); Robert Niemann (September 14, 2007; October 11, 2007), and Robert Vito (June 19-20, 2007, February 5-6, 2008). The United States can provide a full list of depositions attended by Schering-Plough upon the Court's request.

[4] Moreover, to the extent it were amenable to considering its prior rulings in the AWP MDL in this proceeding, this Court rightfully noted that there would be nothing to "preclude someone else from coming up with another record." (7/24/09 Hrg. Tr. at 25:15-19). Indeed, it is questionable how valuable the Court's prior Schering-related findings would be given that they were limited to only three of the 29 Schering brand drugs for which Schering/Warrick now seeks findings of fact and rulings of law.

desire for finality, the "[t]he FCA is not designed to serve the parochial interests of relators but to vindicate civic interests in avoiding fraud against public monies." *Health Possibilities*, 207 F.3d at 340. To that effect, the Court should not permit its "consent" obligations under Section 3730(b)(1) to be used as a vehicle to shortcut the discovery or litigation processes and to render rulings on uncontested issues to be used in other litigation in other jurisdictions.

B. The United States Objects To the Release of 51 Drugs That Were Only Recently Added and Which Were Never Fully Investigated

The Relator filed its first complaint alleging average wholesale price manipulation in 1995 and formally added Schering/Warrick for the first time to the Florida Civil Action in 1997. At that time, the only drug that the Relator alleged against Schering/Warrick was its albuterol sulfate solution. In 2000, the Relator filed the Massachusetts Civil Action against assorted drug manufacturers, including Schering-Plough and Warrick. The only Schering/Warrick drug alleged by the Relator then was the albuterol sulfate inhaler. The United States declined intervention in both *qui tam* actions, with regard to the two albuterol sulfate drugs only, in November 2008. On July 21, 2009, nearly eleven years after it first filed suit against Schering/Warrick, the Relator filed the Proposed Amended Complaint and added, for the first time, 22 additional Warrick generic drugs and 29 Schering brand drugs.

The Government objects to the proposed settlement as it could result in the release with prejudice of the United States' claims in connection with drugs that were only recently added and which the Government did not fully investigate. Until approximately 2006, the primary focus of the Government's investigation was Warrick's albuterol products. The albuterol sulfate drugs were the only ones pled in the Relator's *qui tam* complaints, they were the primary focus of the

early Texas Ven-A-Care litigation against Schering/Warrick and the only drugs released as a result of the settlement, and they were the primary focus of many of the early state complaints filed against Schering/Warrick. While the Government does not dispute that the Relator provided pricing information on some of the other Warrick drugs, or that Schering/Warrick provided utilization data on certain Warrick drugs and spread data on the Schering branded drugs, it is misleading to suggest that the Government actively investigated any drugs other than the albuterol sulfate drugs.

With regard to Warrick's albuterol sulfate drugs, the Government had the benefit of the extensive Texas discovery and litigation. As such, the Government had a very good sense of how Schering/Warrick marketed the albuterol products, what the relevant market was like, and who were Warrick's competitors. Most importantly, the Government had the benefit of all of Warrick's actual sales transaction data for albuterol sulfate. This allowed the Government to know, with a high degree of precision, what were Warrick's actual market prices for albuterol sulfate. In stark contrast, the Government does not have any of Schering/Warrick's actual sales transaction data in connection with any of the additional 22 Warrick drugs or 29 Schering drugs.

Furthermore, notwithstanding that the proposed scope of release would run to the present, the Government does not have any information on Schering's branded drug prices after 2003. This is particularly relevant given that, based on Schering/Warrick's spread analysis on the Schering brand drugs, it appears that the spreads for some of those drugs began to grow starting in 2003. To the extent that the Schering brand drug spreads continued on that trajectory, that information would obviously be relevant to the Government's assessment of the value of the proposed settlement.

C. The Proposed Settlement Amount To the United States Is Not Commensurate With the Scope of Claims Released Under the Proposed Settlement Agreement

Schering/Warrick contend that the proposed Settlement Amount of $55 million "will result in a 'fair, adequate, and reasonable' payment to the United States," Joint Memo. at 20, and is adequate to "resolve the federal-share of any damages allegedly incurred by the Medicaid program, as well as the state-shares in California and Florida." *Id.* at 10.

As a preliminary matter, it is worth clarifying that the United States will not receive the entire proposed settlement amount of $55 million, but rather only $23 million. Based upon information provided by the Relator, California and Florida, the Government understands the $23 million to reflect the federal share of California and Florida's Medicaid damages. Accordingly, from the Government's perspective, the relevant question is whether $23 million is commensurate with the scope of the release contemplated by the proposed settlement.[5] The United States does not believe the $23 million is appropriate and therefore objects to the proposed settlement for this reason as well.

Total Medicaid utilization of Warrick's albuterol products,[6] from 1993 through 2003, for those states that had not settled or otherwise resolved their matters with Schering/Warrick,[7] was

[5] That Schering/Warrick was evidently unaware of the proposed allocation of the $55 million until the July 24, 2009, scheduling conference is surprising insofar as it suggests that Schering/Warrick could equally justify the fairness of the proposed settlement regardless of whether the United States received $1, $1 million, or the entire $55 million.

[6] The Warrick albuterol products span nine NDCs, including: 59930-1560-01; 59930-1560-02, 59930-1515-04, 59930-1500-08, 59930-1500-06, 59930-1510-05, 59930-1517-01, 59930-1517-02, and 59930-1647-02.

[7] This figure does not include the Medicaid albuterol utilization of Arkansas, Connecticut, Missouri, Montana, Nevada, Ohio, Texas, and West Virginia.

approximately $530 million. The Government estimates that of the $530 million, the federal share was approximately 55%, or $292 million.

This Court, in the context of the AWP MDL, has already made a number of findings of fact and rulings of law specifically regarding Schering/Warrick's conduct in connection with the generic albuterol products. *See In re. Pharmaceutical Industry Avg. Wholesale Price*, 491 F.Supp.2d 20 (D. Mass. 2007). Among those findings were that:

> - Warrick reported its AWPs to the pricing publications; *id.* at 70;
>
> - Warrick set its AWPs for a new generic drug at roughly 10 to 20 percent below the branded counterpart drug's AWP; *id.* at 74,
>
> - Warrick never lowered its AWPs despite offering significant discounts that reduced the average sales prices; *id.;*
>
> - "Schering and Warrick were well aware of the role that the spread played in driving purchasing decisions for their products," *id.* at 71.
>
> - Although Warrick did not alter its AWP since 1995, "Warrick's selling prices for all the NDCs of albuterol sulfate declined substantially over time as Warrick sought to match the price of its generic competitors;" *id.* at 75;
>
> - The spreads for every albuterol NDC in every year were all over 100% and reached over 800% in 2003; *id.*

Based upon these findings, this Court held that:

> the persistent existence of mega-spreads is by itself unfair to insurers and patients who are paying based on a median AWP that has no relation to real acquisition costs. Warrick continued this practice despite knowing that patients were overpaying for the drug.

Id. at 109. As such, the Court found Warrick liable under the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 2, for acting "unfairly and deceptively by causing

the publication of false and inflated average wholesale prices for its generic drug albuterol sulfate, which had megaspreads between 100% and 800% throughout the class period." *Id.* at 12.

Against this backdrop, the Government finds $23 million, or 7% of the federal share of the total remaining Medicaid albuterol utilization, to be a difficult recovery to swallow. While accepting that the Relator would face litigation risks, the Government believes that the findings of fact and rulings of law already rendered by this Court regarding Warrick's albuterol products should give the Relator better than a 7% chance of success.[8] Especially so given the depth of experience and knowledge that both the Relator and its counsel possess regarding Schering/Warrick and the albuterol sulfate drugs.

Justifying the proposed $23 million, or even the entire $55 million, becomes even more challenging when the additional 22 Warrick drugs to be covered by the proposed settlement are considered. Based upon Medicaid utilization data provided by Schering/Warrick, the total Medicaid utilization for 16 of the 22 additional drugs is over $576 million.[9] Again assuming that the aggregate federal share was approximately 55%, the total federal utilization for the 16 drugs was approximately $316 million (prior to deducting the Medicaid utilization of states that have already released those drugs).

Not having fully investigated the additional 22 Warrick drugs, the Government does not have complete information regarding how competitive the markets were for these other 22 drugs

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[8] That Schering/Warrick ultimately did not pay any damages in the AWP MDL in connection with the albuterol sulfate drugs is of no import given that Medicaid reimburses for drugs entirely differently than Medicare or the private payors.

[9] The 16 drugs are Betamethasone, Cimetidine, Clotrimazole, Flurbiprofen, Glyburide, Griseofulvin, ISMN, Labatalol, Mexiletine, Oxaprozin, Perphenazine, Potassium Chloride, Selegiline, Sodium Chloride, Sulcrafate Tablets, and Theophylline.

or whether Warrick marketed these drugs differently than the albuterol sulfate products. Moreover, not having access to the actual sales transaction data, the Government does not have complete information on the spreads for each of these drugs. Assuming, however, that Warrick treated these 22 drugs the same way it treated the albuterol sulfate products, the Government would have good cause to believe that Schering/Warrick may have False Claims Act exposure on those drugs as well. Again, the Government accepts that there will be risks that accompany litigating these drugs, many of which Schering/Warrick identify in its brief. Nevertheless, against the backdrop of roughly $600 million in federal Medicaid utilization for all the Warrick drugs to be released, as well as this Court's findings against Warrick generally in the AWP MDL, the Government does not believe that $23 million is commensurate with the scope of the claims to be released under the proposed settlement.

III. The United States Is Not a Roadblock To Settlements

While objecting to the proposed settlement as presently conceived, the United States is willing to continue working with the parties to reach a constructive resolution. Far from being a roadblock or a knot standing in the way of settlement, the United States has been actively involved since 2005 in trying to facilitate a nationwide settlement with Schering/Warrick. Over the years, the United States spent significant time and resources organizing national global settlement demands to Schering/Warrick involving both the federal and state shares and which were agreed to by most, if not all, of the litigating states. When those attempts failed, the United States tried to reach a resolution with Schering/Warrick with regard to the federal claims only. Even now, after having declined to intervene, the United States continues to work with the Settling Parties, as well as the litigating states, to explore the possibility of a global resolution.

It is also worth clarifying that the United States has rarely, if ever, rejected a state's good faith settlements so long as it also recovered the federal share. For example, the United States did not obstruct Ohio or Connecticut from setting their Medicaid claims with Schering/Warrick, nor second guess their settlements. Rather, the opposite situation has occurred more frequently, with states settling with Schering/Warrick without paying back the federal share or settling only the state share of Medicaid damages.

It is against this backdrop that the Government exercises its authority under Section 3730(b)(1) to protect the interests of the United States. In order to obtain the "finality" that Schering/Warrick seek, they must either litigate or negotiate a different settlement. For the reasons discussed above, the proposed settlement is simply not a feasible vehicle or "prototype" for resolving this matter, much less any of the other AWP cases pending before this Court. The United States remains, however, ready to meet with Schering/Warrick to negotiate a global deal and is willing to facilitate discussions with all the litigating states.

CONCLUSION

For the reasons stated above, the United States respectfully withholds its consent to the proposed settlement between the Schering-Plough Corporation, Schering Corporation, Warrick

Pharmaceuticals Corporation (collectively "Schering/Warrick"), the States of Florida and California, and Relator Ven-A-Care of the Florida Keys.

Respectfully submitted,

For the United States of America,

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY

/s/ George B. Henderson, II
George B. Henderson, II
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
(617) 748-3272

JEFFREY H. SLOMAN
ACTING UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

Mark A. Lavine
Ann St.Peter-Griffith
Special Attorneys for the Attorney General
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

TONY WEST
ASSISTANT ATTORNEY GENERAL

/s/ Andy J. Mao
Joyce R. Branda
Daniel R. Anderson
Andy J. Mao
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 307-1088
Fax: (202) 307-3852

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Opposition to the Motion to Approve the Proposed Settlement Between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation, California, Florida, and Relator Ven-A-Care of the Florida Keys" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
Dated: August 28, 2009 George B. Henderson, II